



Class I and II medical devices

Help reduce risks associated with your Class I and II medical devices with UL's quality assurance solutions.



The U.S. Federal Drug Administration (FDA) classifies medical devices into three classes: Class I, Class II, and Class III. The classification for a device depends upon the level of risk that is associated with the device.

Class I devices are considered to be at the lowest level of risk for all medical devices and are only required to comply with the lowest level of regulatory requirements. Whereas, Class II devices are considered to be at a higher risk than Class I devices and therefore require more stringent regulatory controls to prove their effectiveness and safety. For more information about UL's Class III medical device capabilities, please visit <http://www.ul.com/healthcare-and-life-sciences/medtech>.

UL offers a complete portfolio of services for Class I and II medical devices, including quality assurance solutions, regulatory compliance testing and global market access programs. Our team of experts leads the field in developing test methods to help retailers strengthen global compliance programs that include packaging evaluations, label reviews, quality



Testing services

UL's state-of-the-art laboratories offer a variety of testing solutions for Class I and II medical devices such as:

- **Shelf-life and stability studies** — Determine the shelf-life of your Class I and II medical devices utilizes UL's advanced aging technology and capabilities
- **Microbiological testing** — Test for contamination by bacteria, yeast, mold and other potentially hazardous pathogens in your Class I and II medical devices
- **Physical testing** — Evaluate the physical characteristic of medical devices such as appearance, net contents, dimensions and workmanship
- **Analytical testing** — Identify the impurities in the raw materials that make up the medical device or the actual finished product
- **Performance testing** — Assess the performance of your medical devices with accelerated stress testing, benchmarking, failure analysis, aging and life cycle testing and more
- **Packaging testing** — Assess the packaging to help ensure there are no defects with the appearance and workmanship of the container
- **Label review** — Review the labels to validate that all the necessary information is present such as country of origin, adequate directions, warning statements and more
- **Sensory testing** — Trained judges evaluate the different sensory characteristics of the devices such as touch, taste, smell, sound and look

UL Verified Mark for Class I and II medical devices

In an industry where brand and reputation mean everything, leverage the UL Verified Mark to differentiate your product and highlight the confidence you have in its quality. The UL Verified Mark program pairs your product excellence with UL's most trusted science-based processes to verify your marketing claims, provide distinction and set your product apart in the market. Use the UL Verified Mark not only on your product and packaging, but also in your advertising, retail promotions, point-of-sale, and on websites. Letting your consumers know that your marketing claim is now UL Verified gives you an advantage over competitors with self-declared claims.



[Learn more](#) about the UL Verified Mark or [contact us](#) for more information.



Empowering Trust™

UL and the UL logo are trademarks of UL LLC © 2019.